REMARKS

35 USC Section 112

The feature "said connection parts" in line 7 should indeed refer to "said first and second connection parts". Claim 1 has been amended accordingly which is believed to overcome this Section 112 rejection.

Claim 13 has been amended for reflecting "a clamping element for clamping the elongated member to the sternum" which is believed to clarify this claim and overcome this Section 112 rejection.

In line with the amendment to claim 13, also claim 5 has been amended accordingly.

35 USC Section 102

Raymond at al. (US 2005/0159651) teaches a surgical retractor that is entirely unsuitable as an implant in form of a sternum reinforcing device, or even to fulfill the function of keeping any body parts together as it is designed for doing the upright opposite. Raymond et al. teaches a surgical retractor which is best described as a tool that is used in surgery. Retractors are specifically used for "retracting", i.e. for creating access to specific body parts during surgery, for which purpose typically patient's body parts like organs, tissue and bones are kept apart from each other for providing access to a surgical working space. The function and the design of the retractor taught by Raymond et al. can be best understood by looking at figures 37T. A relevant passage to that extent can be found in paragraph [0181], reading (emphasis added):

"After retractor 3730 is expanded and the facet joint is visible, blade pusher 3774 may be used to deploy the telescoping blade extensions further to, for example, prevent soft tissue creep in the working space."

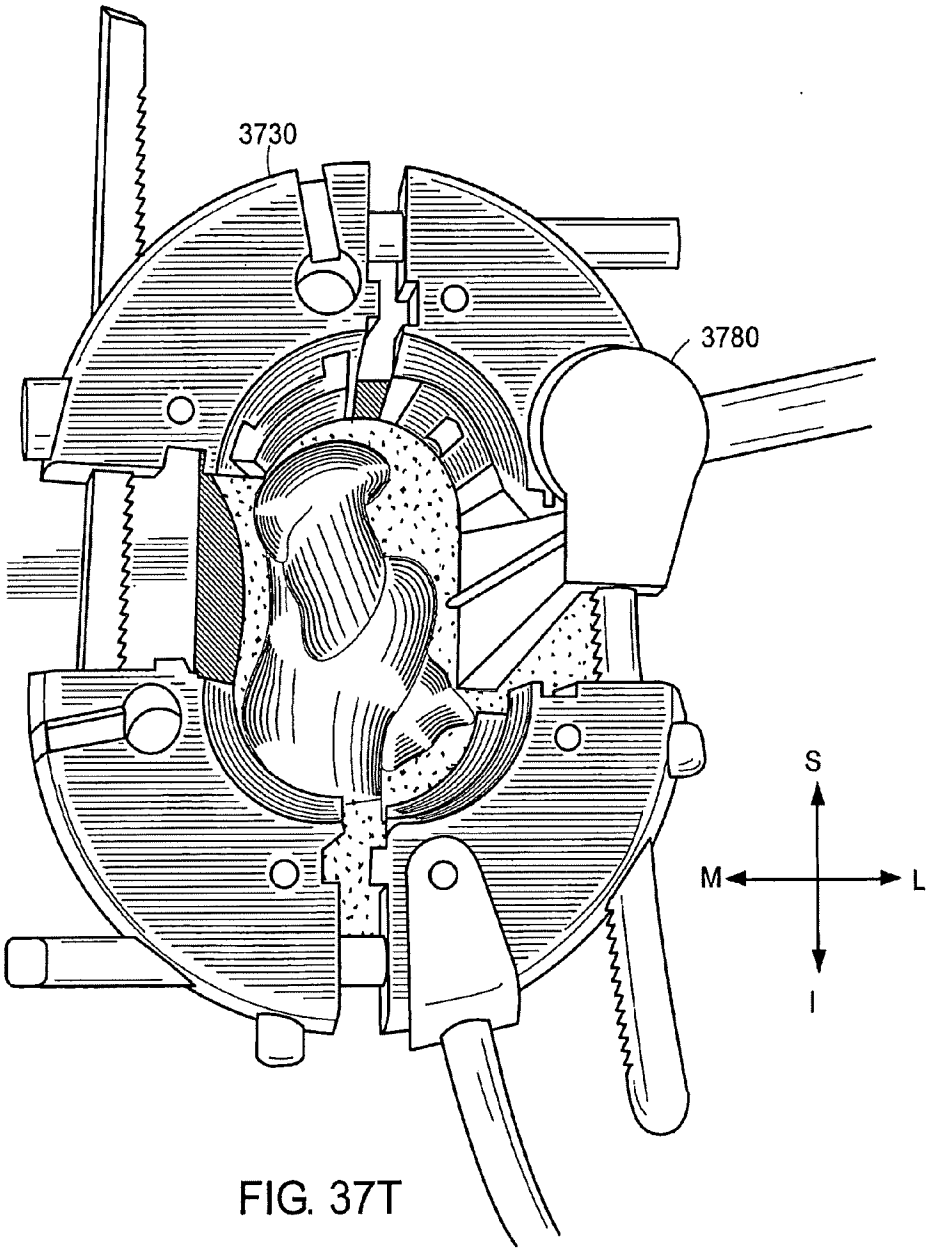

FIG. 37T

The online dictionary Wikipedia defines a retractor as follows:

"A retractor is a surgical instrument by which a surgeon can either actively separate the edges of a surgical incision or wound, or can hold back underlying organs and tissues, so that body parts under the incision may be accessed. The two are each available in many shapes, sizes, and styles. The general term ***retractor*** *usually describes a simple handheld steel tool possessing a curved, hooked, or angled blade fitted with a comfortable handle, that when in place maintains the desired position of a given region of tissue. These simple retractors may be handheld, clamped in situ, or suspended at the end of a robotic arm. The term* ***retractor*** *is also informally used, though, to describe the distinct, hand-cranked devices such as* ***rib spreaders*** *(also known as thoracic retractors, or distractors) with which surgeons may forcefully drive tissues apart to obtain the exposure."*

By the very definition of the retractor, it already becomes apparent that it is unsuitable as an implant, and it actually performs the upright opposite function of the claimed device, namely spreading body parts apart which is in contrast to the sternum reinforcing device according to the present invention that does the opposite, namely to keep body parts, here a split fractured sternum, together and reinforce it.

The retractor by Raymond et al. is already for that reason completely unsuitable for as a sternum reinforcing device. Other features that make it already on its face unsuitable is the bulky nature of this device, together with no teaching how this device could be attached to a sternum. Consequently, a sternum is not even mentioned in Raymond at al., but this prior art reference is described as suitable *"to retract tissue near the spine of a human"*.

It is therefore respectfully disagreed with the Examiner that Raymond at al. would disclose "a sternum reinforcing device to be used after a sternum

sternotomy or a sternal fracture". No proposal was given how this device could be attached to a sternum at all, let alone taking into account that a patient has to breathe which would be virtually impossible with this Raymond et al. device fixed to a sternum even under the assumption that the skilled person would add attachment elements which are not taught in Raymond et al. that would allow to connect this device to a sternum. Again, the lack of teaching any attachment elements in Raymond et al. is consistent with its purpose, namely to "... *prevent soft tissue creep in the working space"* by pushing soft tissue aside by means of the retractor blades.

The retractor blades 704, 706 in Raymond et al. - which the Examiner annotated as "projecting portion" - do not comprise any connecting means that would allow fixing of these blades to any body part of a patient. The disclosed device just has the function of pushing tissue apart, namely *"to reposition muscular tissue, vessels, nerves and other tissue with the aid of retractor blades"* as for instance described in paragraph [0003] of Raymond et al.

In the following, it is particularly summarized by referring to the claim language with comments inserted in brackets and in italics how the subject matter of the current independent claim 1 differs from Raymond et al.:

1. (Currently Amended) A sternum reinforcing device to be used after a sternotomy or a sternal fracture *[Raymond et al. teaches a retractor, not a reinforcing device, and particularly not in device that can be used in connection with the sternum let alone be fixed to a sternum]* said device comprising:

at least an elongated member apt to be used as a unit of a reinforcing group *[Raymond et al. fails to reinforce, but to the opposite "retracts". The elongated member in Raymond et al. are retractor blades unsuitable for any reinforcement]*, said elongated member being designed to be located on a surface portion of an anterior longitudinal lateral edge of a sternum *[Raymond et al. fails to disclose any use in connection with a sternum]* and is provided with a first and a second connection parts *[Since*

Raymond et al. teaches a retractor, it does not comprise any connection parts];

said first and second connection parts being in the form of arms [*Raymond et al. is best understood by looking at figure of 37T. For spreading the retractor blades apart, ratchet arms are provided, which should not be confused with "connection parts"]* wherein a first one of the arms extends in a first direction with respect to a central portion and a second one of the arms extends in a second direction with respect to said central portion, the second direction being opposite to the first direction; *[Raymond et al. does not comprise a first and a second arm, and certainly, no arms from any connection part extend in opposite directions. In contrast, Raymond et al. comprises exactly four retractor blades to define kind of an oval surgical working space between the four retractor blades and the ratchet arms of adjacent ratchet mechanisms extend in a right angle to each other and not in opposite directions.]*

said first connection part of said elongated member being adapted to join with a second connection part of a preceding elongated member of the reinforcing group along the longitudinal lateral edge of the sternum; *[As discussed above, Raymond et al. teaches pushing apart respective adjacent retractor blades but is unsuitable for any reinforcement, particularly reinforcement of a sternum]*

said second connection part of said elongated member being adapted to join with a first connection part of a following elongated member of the group along the same longitudinal lateral edge of the sternum;*[In the annotated figure 8 in the office action, the Examiner has annotated the retractor blade 704 as the elongated member. As discussed above, these retractor blades are pushed apart and do not comprise any connection element themselves even when the ratchet mechanism to which the retractor blades are connected are added to the elongated member.]*

said elongated member being further provided with a projecting portion designed to be fitted in an intercostal space adjacent to the longitudinal lateral edge of the sternum. *[Particularly looking at figure 37T of Raymond et al., it becomes clear that the Raymond et al. device is unsuitable for having the retractor blades enter any intercostal space adjacent to the longitudinal lateral edge of the sternum.]*

The Dependent claims

Regarding claim 2, Raymond et al. fails teaching a prismatic coupling with corresponding connection parts. As discussed above, Raymond et al. teaches a retractor having 4 retractor blades. These blades and their ratchet mechanism do not comprise any arms.

Regarding claim 3, if as annotated by the Examiner in the office action in figure 8, the elongated member in Raymond et al. should include the ratchet mechanism, this mechanism is certainly not made from bent plate material, and even the retractor blade (e.g.704) itself is not clear how it is has been made. The Examiner has pointed to paragraph 125 in Raymond et al. This paragraph just mentions metal as a material, without referring particularly to the retractor blade and does not mention how this retractor plate has been manufactured.

Regarding claim 4, as discussed above, the Raymond et al. device is unsuitable for having any parts thereof protrude into an intercostal space, and there are certainly no connection parts as claimed in claim 4 since Raymond et al. teaches a device having 4 blades and not any device allowing to connect several elements in a modular fashion to any adjacent element.

Regarding claim 5, as discussed above, the Raymond et al. retractor does not comprise any attachment means that would allow attaching any part of the retractor to any body part of a patient due to its very nature to "retract", i.e. Raymond et al. fails teaching any clamping means, let alone designed as wires.

Regarding claim 6, no U-shape is shown at all in Raymond at al., the retractor blades are not suitable for entry into an intercostal space, and the retractor blades do not comprise any projecting portion in the form of legs that could be bent in opposite directions.

Regarding claims 7-8, no prior art has been cited regarding these claims and the Examiner has indicated earlier in a telephone interview that these claims would be allowable.

Regarding claim 9, the ratchet arms in the Raymond et al. retractor cannot be compared to a connection part, and the ratchet arms are not part of the elongated members.

Regarding claim 10, no flat rectangular profile can be found for the ratchet arms, but a thick rectangular profile that is necessary for providing the rigidity, and unsuitable for attachment to a sternum or any other body part.

Regarding claims 11-12, as discussed above, the ratchet arms are separate elements not to be confused with connection parts according to the present invention allowing any random number of connections to other separate elements.

Regarding claim 13, Raymond et al. fails teaching any free edges that form legs, there is no part in Raymond et al. at all that can be bent outwards, and even more so, no part that can be bent to enclose a clamping element for clamping any part of the Raymond et al. device to a sternum or any other body part.

Summary

Apart from the clear distinction of the invention as presently claimed over the prior art, the object solved by the present invention should be kept in mind: One object is for instance described on page 2, lines 17 to 20 of the underlying original PCT application of the present application, reading:

"Therefore, an object of the present invention is to manufacture a device adapted to be used in the sternal closure that provides a lateral reinforcement of the sternal halves as well as to both anterior and posterior portions of the sternum."

The Raymond et al. device would not provide any solution for this problem since:

- the function of the retractor in Raymond et al. is in upright contrast to the present invention, namely to retract tissue rather than providing any kind of closure such as a sternal closure;

- no element is disclosed in Raymond et al. that could be connected to any body part of a patient;

- the Raymond et al. device comprises a fixed number of retractor blades extending in a right angle to adjacent retractor blades that have to interact with each other in order to define a surgical working space therebetween but fails to allow connecting any desired number of reinforcement elements in a modular fashion, particularly in a linear fashion;

- the Raymond et al. device is much too bulky for being acceptable inside a patient's body, particularly at a sternum that needs to allow motion so that the patient can breathe; and

- the Raymond et al. device teaches a surgical tool, not any implantable reinforcement. The surgical tool needs to be removed immediately at the end of the surgical process and cannot remain within the patient's body after the surgery has been completed.

Issued parallel patents in several countries applying high search and examination standards

It is understood that technically the Patent Prosecution Highway request cannot be filed due to timing issues. It is pointed out though that parallel patents have been issued in the European Patent Office, the Russian Patent Office, and the Chinese Patent Office. The USPTO has Patent Prosecution Highway agreements both with the European Patent Office EPO and the Russian Patent Office ROSPAT – which is an indicator that these Patent Offices conduct a thorough search and examination . Further,

it is known that also the Chinese Patent Office SIPO – although not a current PPH country - conducts a thorough search and examination. Since three major Patent Offices independently conducting a thorough search and examination came to the conclusion that a patent should be allowed at a similar or even broader scope as currently requested in US - this should be taken into consideration as another indicator of patentability, particularly since the prior art that was cited (Raymond et al.) is a retractor that by its design and function - lacking connection means and been designed to retract - is unsuitable to keep together and reinforce a sternum or even to be attached to a sternum at all.

Request to withdraw the finality of the Office Action dated 9/3/10

On page 11 under "Response to arguments" the Examiner states: "Applicant's arguments with respect to claim 1 above have been considered but are moot in view of the new grounds of rejection." Since Raymond et al. was cited for the first time in this office action and the applicant did not get a chance to comment on Raymond et al., it is respectfully requested to withdraw the finality of this office action dated September 3, 2010 and treat it as a non-final office action.

Conclusion

Applicant respectfully requests that the Examiner issue a Notice of Allowance for the pending claims 1 – 13. Should the Examiner require further information, the Examiner is invited to contact the Applicant's representative at the number listed below.

Respectfully submitted,

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